



# HIPAA Security Topics - 2

Web Resources, Implementation Guide and Biomedical Devices

HIPAA Training: 2005 Summer Sessions

TMA Privacy Office

## **Agenda**

- TMA Privacy Office HIPAA Security Web Site
- Risk Information Management Resource (RIMR)
- HIPAA Security Implementation Guide
- Biomedical Devices

## **Training Objectives**

- Upon completion of this course you will be able to:
  - Identify available resources to aide in Security Awareness
  - Identify available training briefings
  - Identify available resources to aide in implementation of HIPAA Security
  - Describe the relationship between HIPAA Security and biomedical devices

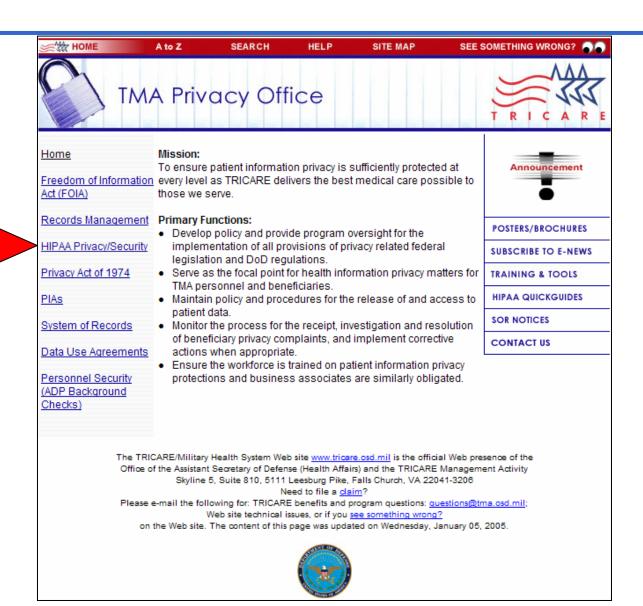
# TMA Privacy Office HIPAA Security Web Site

# TMA HIPAA Security Web Site Objectives

- Upon completion of this lesson, you will be able to:
  - Locate information pertaining to security topics and HIPAA security management
  - Locate information pertaining to HIPAA support tools and training
  - Locate information pertaining to HIPAA news, conferences and e-news

# http://www.tricare.osd.mil/tmaprivacy

(1 of 3)



# http://www.tricare.osd.mil/tmaprivacy

(2 of 3)



# http://www.tricare.osd.mil/tmaprivacy

(3 of 3)



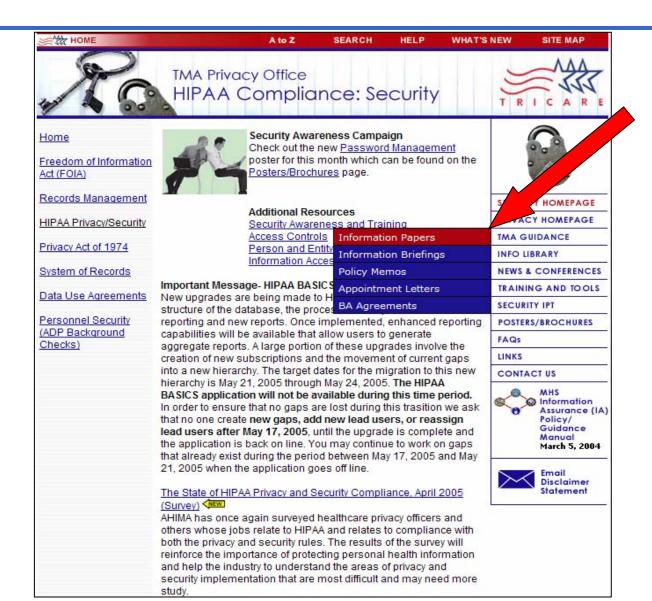
### TMA Guidance (1 of 2)



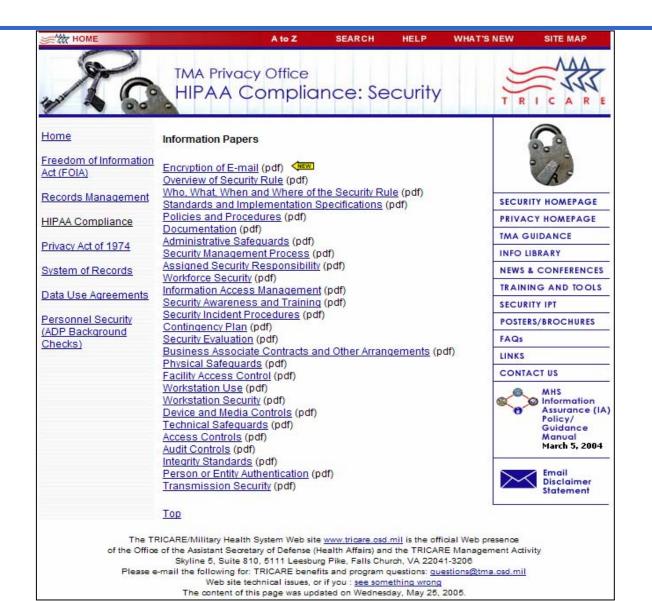
# TMA HIPAA Security Web Site TMA Guidance (2 of 2)

- Information Papers
  - HIPAA Security Overview and 25 other related information papers
- Information Briefings
  - Conference and informational briefings
- Policy Memos
  - Policy memos relating to HIPAA Security implementation
- Appointment Letters
  - MTF/DTF, TRICARE Regional Office and Service Headquarters
- BA Agreements
  - Joint HIPAA Privacy and Security contract clause

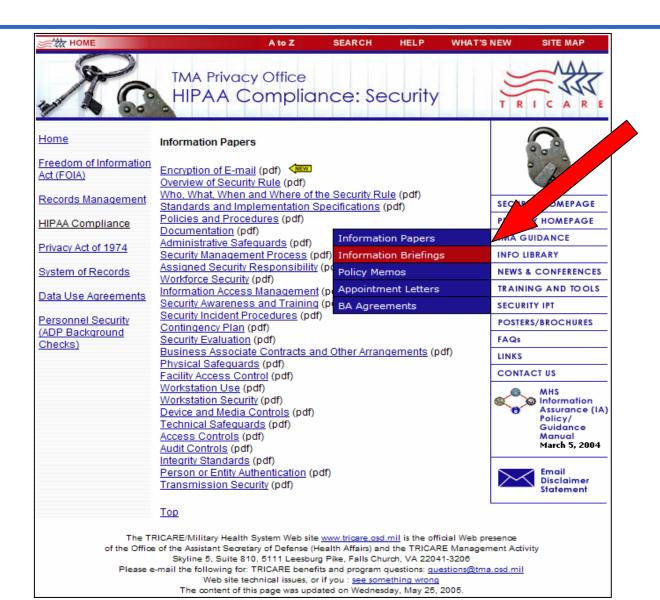
## Information Papers (1 of 2)



### Information Papers (2 of 2)



# Information Briefings (1 of 2)

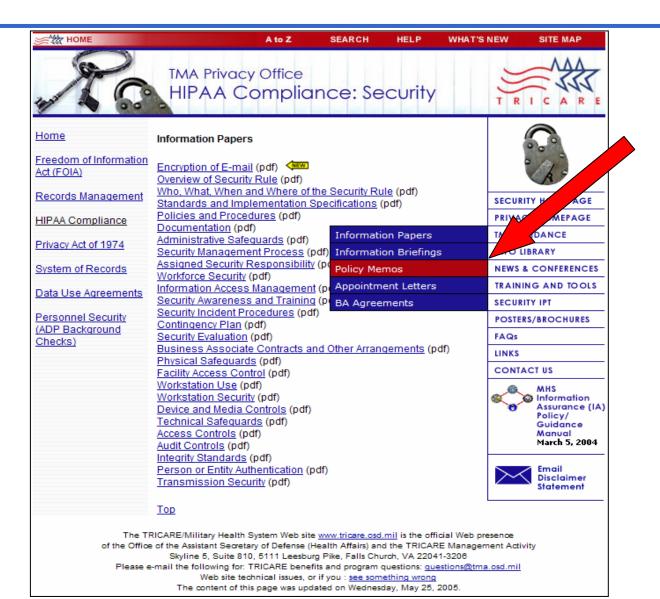


# Information Briefings (2 of 2)

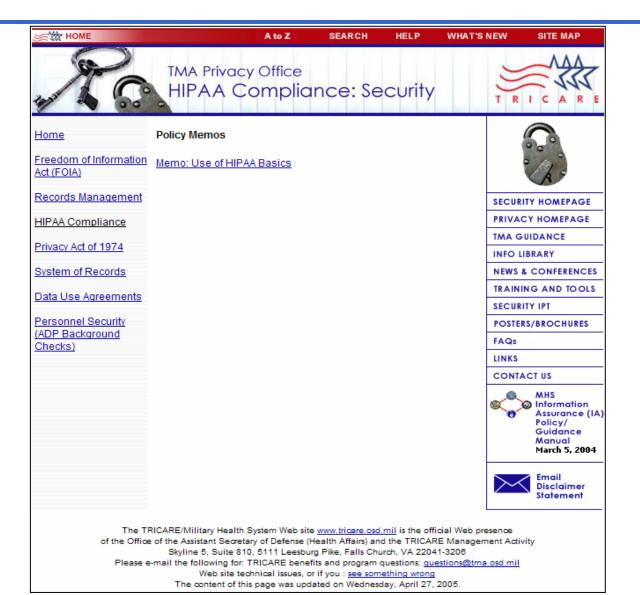


Web site technical issues, or if you: see something wrong
The content of this page was updated on Wednesday, April 27, 2005.

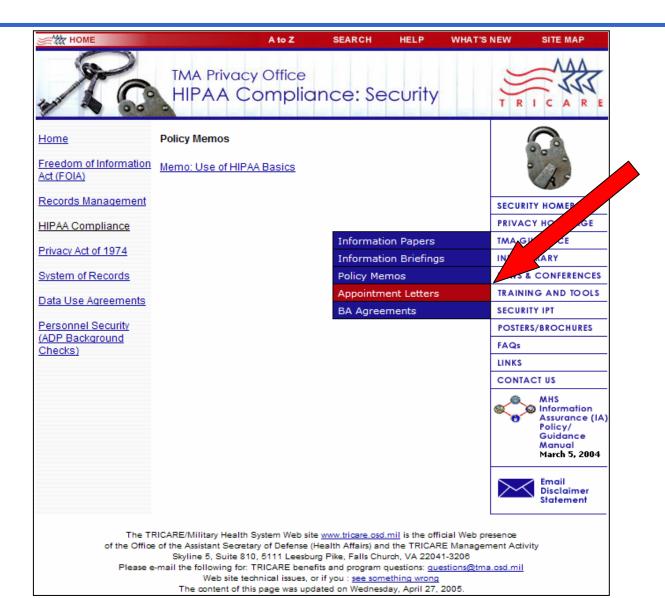
# TMA HIPAA Security Web Site Policy Memos (1 of 2)



# TMA HIPAA Security Web Site Policy Memos (2 of 2)



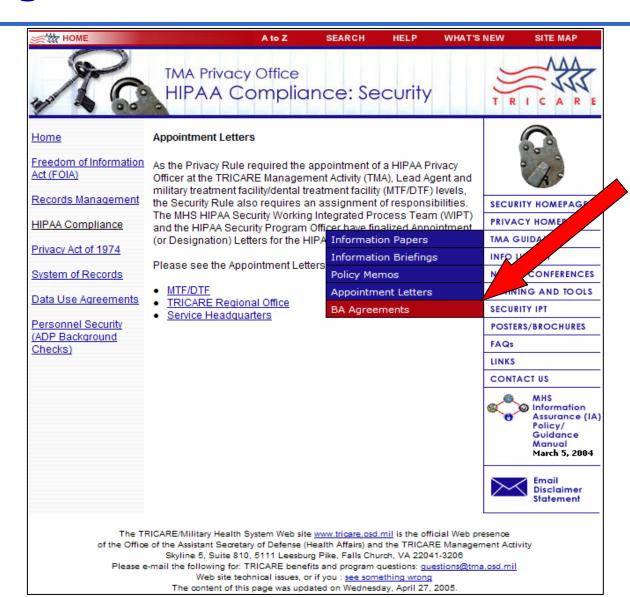
## **Appointment Letters** (1 of 2)



## **Appointment Letters** (2 of 2)



### BA Agreements (1 of 2)



### BA Agreements (2 of 2)



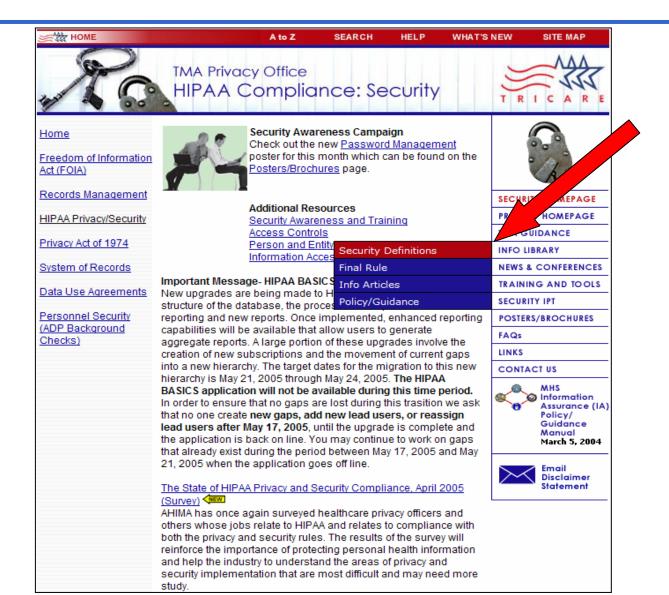
# Information Library (1 of 2)



# TMA HIPAA Security Web Site Information Library (2 of 2)

- Security Definitions
  - HIPAA definitions list
- Final Rule
  - 45 CFR Parts 160, 162, and 164
- Info Articles
  - Information articles covering various security topics
- Policy and Guidance
  - DoD, Service-specific, and other Federal policy documentation

## Security Definitions (1 of 2)



### Security Definitions (2 of 2)



#### HIPAA PRIVACY DEFINITIONS

#### <u>A B C D E F G H I J K L M N O P Q R S T U V W X Y Z</u>

Α

#### Access

The ability or the means necessary to read, write, modify, or communicate data/information or otherwise use any system resource.

#### Access Authorization

Under HIPAA, implementing policies and procedures for granting access to electronic protected health information, for example, through access to a workstation, transaction, program, process, or other mechanism.

#### Access control

Under HIPAA, limplementing policies and procedures for electronic information systems that contain EPHI electronic protected health information to only allow access to persons or software programs that have appropriate access rights.

#### Access Control and Validation Procedures

Under HIPAA, implementing procedures to control and validate a person's access to facilities based on their role or function, including visitor control, and control of access to software programs for testing revision.

#### Access Establishment and Modification

Under HIPAA, the security policies and procedures that, based upon the entity's access authorization policies, establish, document, review, and modify a user's right of access to a workstation, transaction, program or process.

#### Access Level

A level rank or category label associated with an individual who may be accessing information (for example, a clearance level) or with the information, which may be accessed (for example, a classification level).

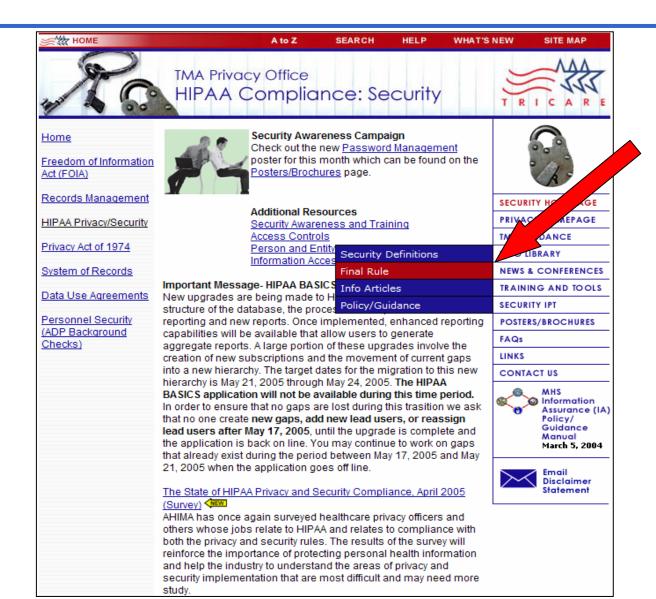
#### Access Modification

The security policies, and the rules established therein, that determine types of, and reasons for, modification to an entity's established right of access to a terminal, transaction, program, or process.

#### Accountability

The property that ensures that the actions of an entity can be traced uniquely to that entity.

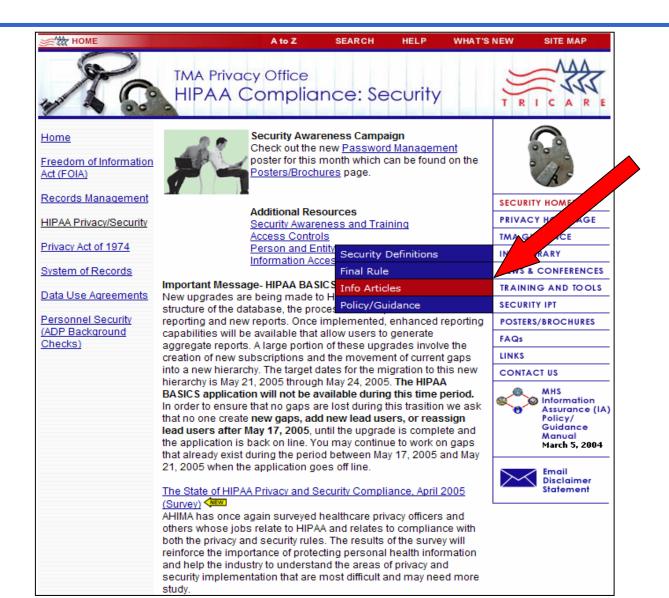
# TMA HIPAA Security Web Site Final Rule (1 of 2)



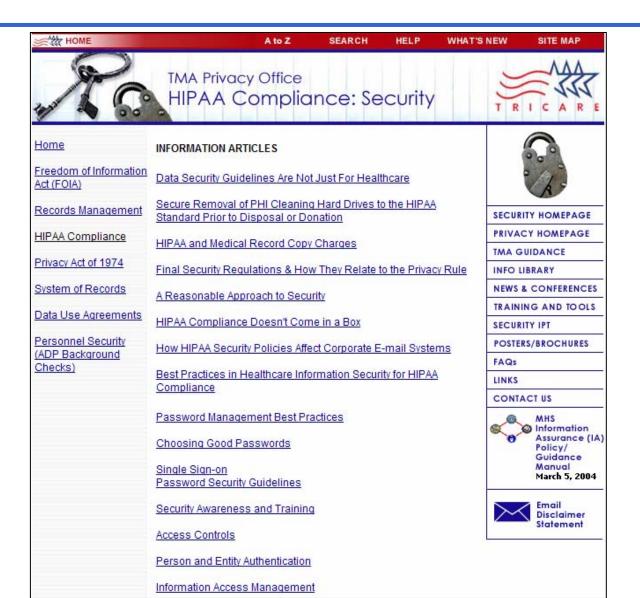
# TMA HIPAA Security Web Site Final Rule (2 of 2)



# TMA HIPAA Security Web Site Info Articles (1 of 2)



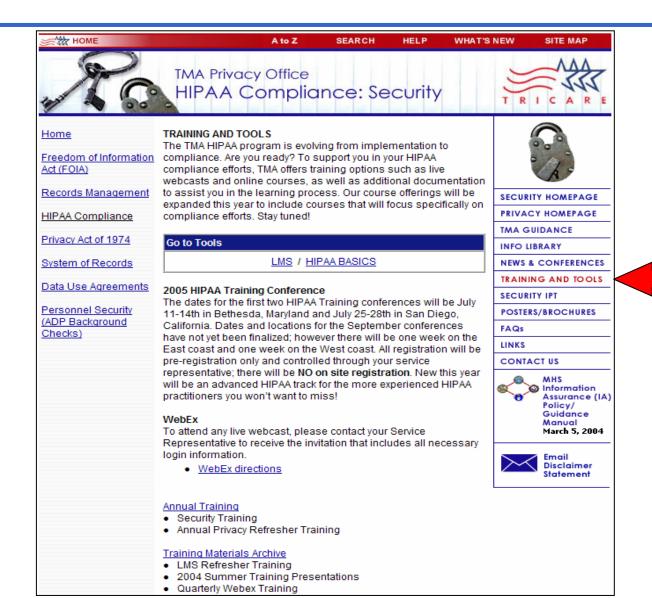
# TMA HIPAA Security Web Site Info Articles (2 of 2)



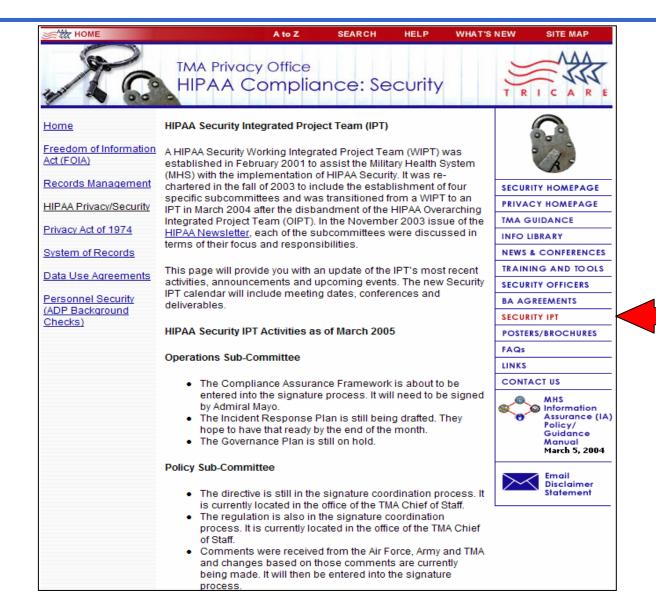
### **News and Conferences**



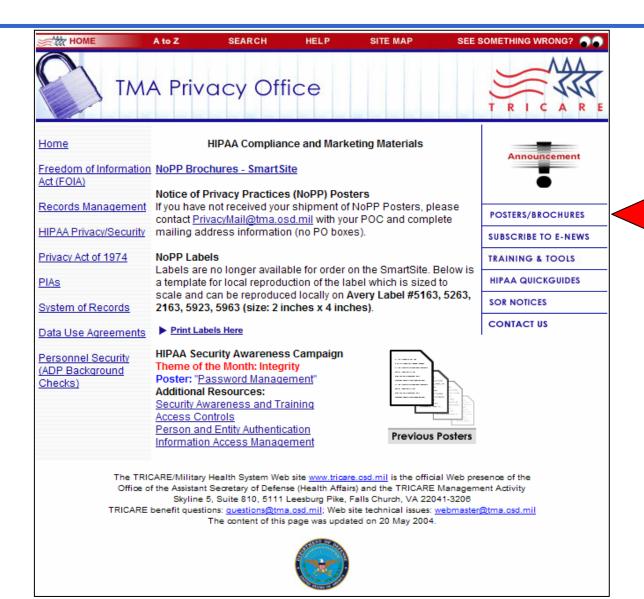
# **Training and Tools**



# TMA HIPAA Security Web Site Security IPT



# TMA HIPAA Security Web Site Posters/Brochures



## **Poster Background**

- Developed by HIPAA Security IPT Training and Education Subcommittee
- Purpose:
  - Aide in increasing awareness of good security practices
  - Target audience is information system users
  - Designed as a long term campaign (1 for each month of the year)
  - Designed to integrate into other existing training and awareness programs

# TMA HIPAA Security Web Site Poster Content

- Posters grouped into three themes: Confidentiality, Integrity, and Availability, with one comprehensive poster that combines all three
- Contemporary design to catch the eye
- One color for each theme
- Each poster has the theme, a topic, slogan and text

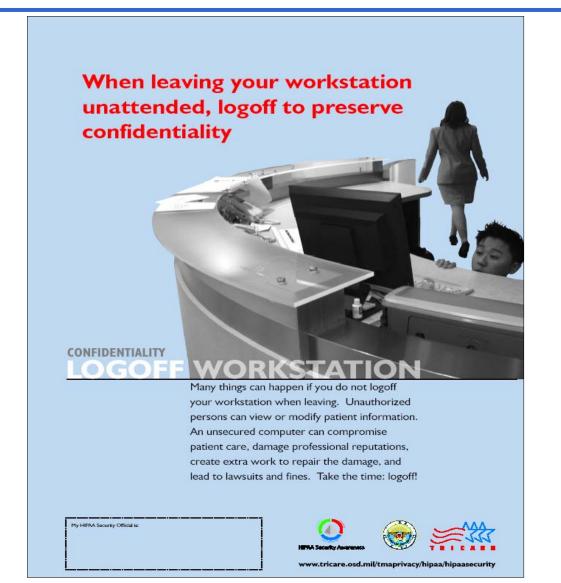
### **HIPAA Security Poster Campaign**

### **Visitor Control Poster**



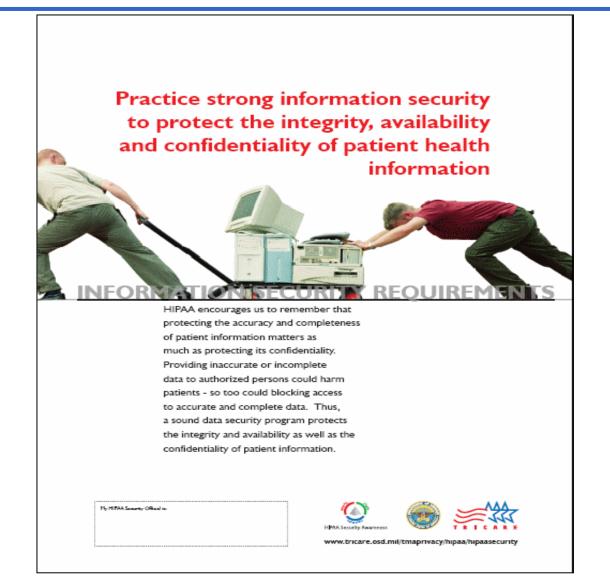
#### **HIPAA Security Poster Campaign**

## **Logoff Workstation Poster**



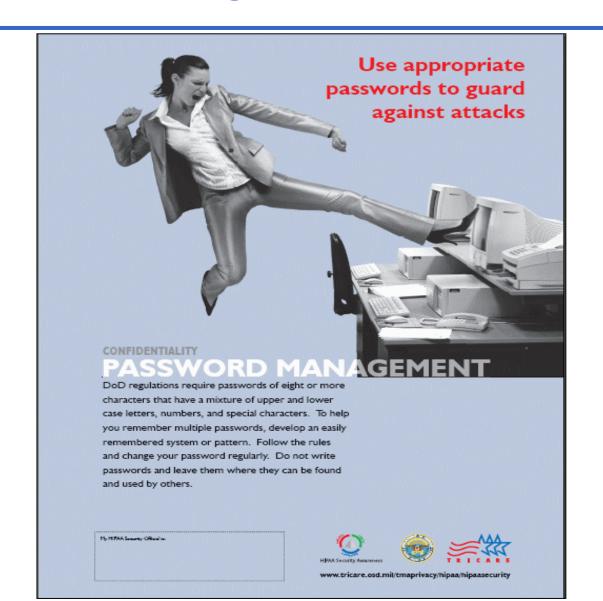
### **HIPAA Security Poster Campaign**

# Information Security Requirements Poster



### **HIPAA Security Poster Campaign**

## **Password Management Poster**



## TMA HIPAA Security Web Site Poster Distribution

- Distributed once a month starting last year with a comprehensive poster
- Distribution coordinated with related information via enewsletter
- 3 copies of each poster to each MTF
  - Limited number of additional posters available on request
- Mailed to each MTF's Privacy or Security Officer
- If not receiving posters contact privacymail@tma.osd.mil
- Electronic copies available on web site
- Currently on poster 10 of 12

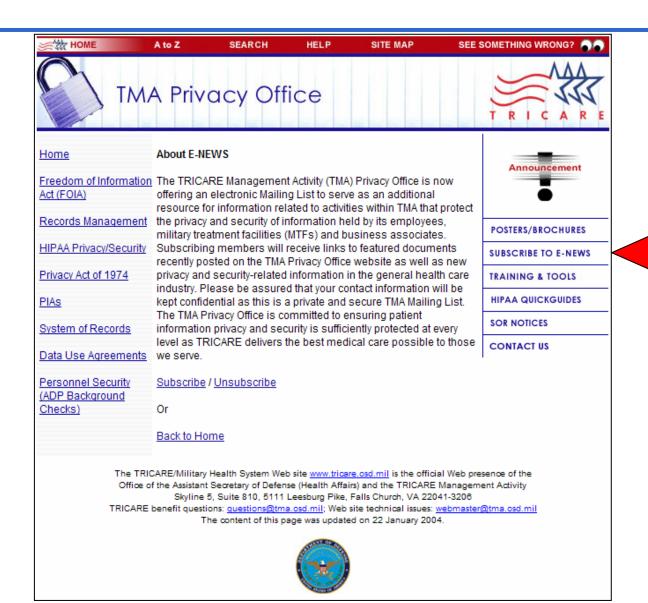
## **How to Integrate Posters**

- Review elements of your current programs and or resources to:
  - Determine which elements can be used to promote awareness of the posters (e.g., existing monthly staff newsletters)
  - Use posters and related material to support other programs that are related to either security or HIPAA
  - Build on poster themes and topics in your own awareness campaign
- Post in elevator lobbies and other high traffic areas
- Color printing is available from the TMA HIPAA Website in an 8.5x11 version

### **E-News** (1 of 2)

- Electronic Mailing List to serve as additional resource for information and activities within TMA pertaining to maintaining the privacy and security of information held by its employees, military treatment facilities (MTFs) and business associates
- Subscribing members receive links to featured documents recently posted on the TMA Privacy Office web site
- Subscribing members also receive new privacy and security-related information in the general health care industry

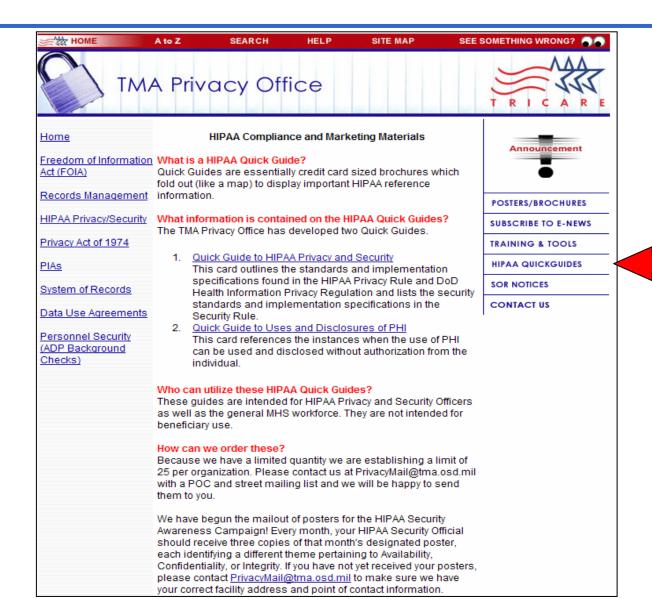
# TMA HIPAA Security Web Site **E-News** (2 of 2)



### HIPAA Quick Guides (1 of 2)

- Quick Guides are essentially credit card sized brochures which fold out (like a map) to display important HIPAA reference information
- These guides are intended for HIPAA Privacy and Security Officers as well as the general MHS workforce and they are not intended for beneficiary use

### HIPAA Quick Guides (2 of 2)



## **Summary**

- You should now be able to:
  - Locate information pertaining to security topics and HIPAA security management
  - Locate information pertaining to HIPAA support tools and training
  - Locate information pertaining to HIPAA news, conferences and e-news

# Risk Information Management Resource (RIMR)

## **Objectives**

- Upon completion of this lesson, you should be able to:
  - Identify what systems and processes form RIMR
  - Describe the information the database stores and provides
  - Identify who developed the RIMR and how it helps you maintain compliancy

# What is RIMR? (1 of 2)

- Web portal provides access to:
  - Information Assurance (IA) resources (policies, case studies, white papers)
  - Plans, Policies and Procedures Working Group (P3WG)
     HIPAA Privacy and Security Reports
  - Operationally Critical Threat Asset and Vulnerability Evaluation (OCTAVE<sup>SM</sup>) (including methodology, automated tool, risk database and support center)
- OCTAVE<sup>SM</sup> Automated Tool (OAT)
  - Downloads to desk top
  - Documents the results of each OCTAVE<sup>SM</sup> and stores in database
  - Steps user through the process
  - Prints final reports

# What is RIMR? (2 of 2)

- Risk Database
  - Stores completed risk assessments
  - Provides aggregate reports
  - Can be used to research common vulnerabilities
  - Trend analysis
  - Supports enterprise wide problem solving and mitigation
  - Justification for funding initiatives

## Where is RIMR? - http://rimr.tatrc.org

Policy Library
References
Presentations
Risk Assessment
Training
MISRT Training
Technical Watch
Coming Events
C & A
OCTAVE<sup>SM</sup>
Information Center
Site Search

Home



Welcome to the Risk Information Management Resource (RIMR)!

RIMR enables the Department of Defense Military Health System to centrally manage and distribute worldwide access to a range of information sources for assessing, enhancing, studying and archiving data about defense health information assurance.

The primary audience for RIMR includes members of Medical Information Security Readiness Teams (MISRT) at all medical treatment facilities and defense, government and contractor employees with responsibility for protecting health information security.

RIMR includes the following resources:

<u>Policy Library</u> contains copies of all policies containing guidance on protecting the confidentiality, integrity, and availability of health care records and information from the Department of Defense, Army, Air Force, Navy. The policy library also has an authenticated webboard collaborative area.

Reference Library contains presentations, reports, documents and hyperlinks concerning important and interesting topics in health information assurance, such as the data security regulations of the Health Insurance Portability and Accountability Act of 1996. A search engine helps you efficiently use the Reference section.

<u>Risk Assessments</u> constitute the heart of information assurance. In this section, you will find the implementation guide for OCTAVEsm a self-directed information security risk assessment, the OCTAVEsm Information Center and capability to upload OCTAVEsm results to databases.

<u>Training</u> Center provides detailed information about future workshops on health information protection including logistical and registration details, HIPAA Training, and online Cyber Seminars.

### Reference Library

Policy Library
References

Presentations
Risk Assessment

Training

MISRT Training
Technical Watch

Coming Events

C & A

OCTAVE<sup>SM</sup>

Information Center

Site Search

Home

#### REFERENCE LIBRARY

Welcome to the RIMR Reference Library!

The Reference Library contains multiple types of resources addressing issues in protecting the confidentiality, integrity and availability of health care records and information.

- <u>Presentations</u> includes power point slides of talks given by various individuals on the Department of Defense health information assurance program.
- <u>Reports</u> includes documents on specific topics in DoD health information assurance such as the Final Reports of the P3 Working Group that compare HIPAA data security and HIPAA privacy regulations with DoD and service policies.
- <u>Documents</u> includes resources from various sources on general and specific topics in health information assurance.
- <u>Hyperlinks</u> connects you directly to resources concerning health information assurance on the World Wide Web.

You may consult the Reference Library in two ways:

- Click on the type of resource you wish to consult and make a selection from the list of titles, or
- Use the <u>Search</u> engine that enables you automatically to find resources by author, title, subject or keyword.

### RIMR OCTAVESM

\*\*Policy Library References

■ Presentations▶ Risk Assessment

Training

MISRT Training

Technical Watch
Coming Events

C & A
OCTAVE<sup>SM</sup>
Information Center
Site Search
Home

#### RISK ASSESSMENT LIBRARY

Welcome to the RIMR Risk Assessments Library!

The Risk Assessments Library contains a variety of resources designed to help you understand and execute information security risk assessments in your facility.

- OCTAVE sm Implementation Guide provides everything you need to
  execute a self-directed information security risk assessment at your facility,
  including detailed instructions, explanatory slides, worksheets, templates
  and examples.
- <u>Automated OCTAVE</u> sm <u>Interface</u> enables you to enter and save results from OCTAVEsm workshops directly into a computerized database.
- OCTAVE sm Information Center provides online information and support as you use OCTAVEsm to improve health information assurance in your facility.
- Other risk assessment tools\* provides information about other tools available for information security risk assessment.

### Who Developed RIMR

- Congressionally funded through Defense Health Information Assurance Program (DHIAP)
- Currently located at Ft. Detrick
- DoD owned not vender owned
- Developers
  - Advanced Technology Institute, Charleston SC
  - KRM Associates, Inc, Shepherdstown WV
  - Software Engineering Institute at Carnegie Mellon (CERT),
     Pittsburgh PA

## P3WG Final Report Background

- DHIAP and the DoD/HA HIPAA Overarching Integrated Process Team (OIPT) sponsored the formation of the interdisciplinary and inter-service Policies, Procedures, and Practices Workgroup
- Compared all pertinent DoD and service level regulations with the HIPAA Data Security Rule
- Identified gaps and discrepancies and made recommendations for changes

## **P3WG Final Report Content**

- Executive summary and methodology
- Chapter for each rule and associated implementation specifications
  - HIPAA wording with plain English explanation
  - All mapped citations
  - Compliance analysis with recommendations
- Analysis of results

## **P3WG Final Report Utilization**

- Used at multiple levels
- Guide central policymakers in making revisions
- Critical input includes analysis of results and recommendations
- Use as background information when updating local policies
  - Identifies upper level policies and procedures MTF's should follow
  - Identifies gaps local policies and procedures must fill
- Feed remaining gaps into risk analysis

## **Summary**

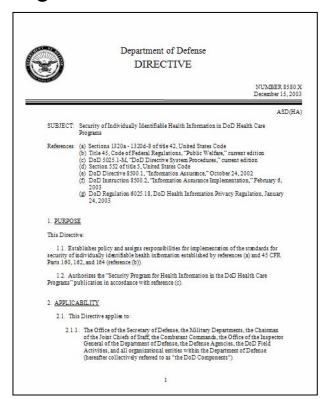
- You should now be able to:
  - Identify what systems and processes form RIMR
  - Describe the information the database stores and provides
  - Identify who developed the RIMR and how it helps you maintain compliancy

# HIPAA Security Implementation Guide **Objectives**

- Upon completion of this lesson, you should be able to:
  - Identify the purpose and organization of the Implementation Guide

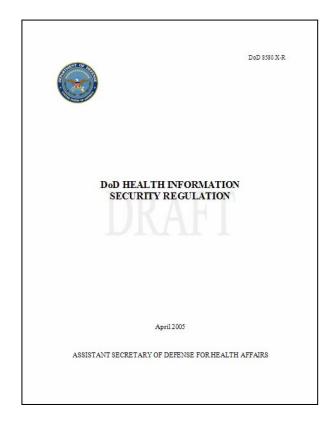
## HIPAA Security Implementation Guide **Purpose** (1 of 3)

- Provide guidance with the implementation of:
  - DoD 8580.X-D, Security of Individually Identifiable Health Information in DoD Health Care Programs



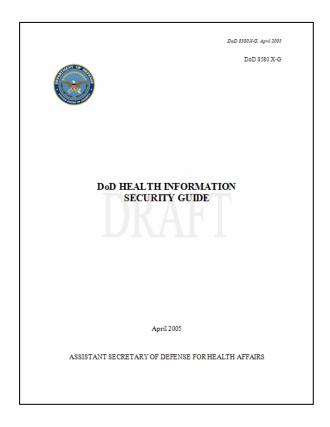
# HIPAA Security Implementation Guide **Purpose** (2 of 3)

- Provide guidance with the implementation of (Cont.)
  - DoD 8580.X-R, DoD Health Information Security Regulation



# HIPAA Security Implementation Guide **Purpose** (3 of 3)

Contains "actionable steps" towards compliance



### Organization of Guide (1 of 3)

- Chapter 1: General Information
  - Background
    - History of HIPAA
  - What is HIPAA Security
    - Definition
    - Key concepts and terms
    - Organization of requirements within the security rule
  - Compliance
    - How to achieve HIPAA Security compliance

# HIPAA Security Implementation Guide Organization of Guide (2 of 3)

- Chapter 1: General Information (cont.)
  - Existing DoD Requirements
    - Explanation of why most HIPAA security standards and implementation specifications are required and not addressable
- Chapter 2: Administrative Safeguards
  - Administrative standards and implementation specifications with general guidance on how to achieve compliance
- Chapter 3: Physical Safeguards
  - Physical standards and implementation specifications with general guidance on how to achieve compliance

# HIPAA Security Implementation Guide Organization of Guide (3 of 3)

- Chapter 4: Technical Safeguards
  - Technical standards and implementation specifications with general guidance on how to achieve compliance
- Chapter 5: Policies and Procedures, and Documentation
  - Policies and Procedures, and Documentation standards and implementation specifications with general guidance on how to achieve compliance

## HIPAA Security Implementation Guide Organization of Standards (1 of 4)

### C2.2. ASSIGNED SECURITY RESPONSIBILITY

The number and type of personnel required to implement an organization's security policies in a manner consistent with reference (e) depends on the size and structure of the organization. Document and validate the actual workforce numbers with a breakdown of responsibilities as part of the security management process. The HIPAA Security regulation states the following:

### Organization of Standards (2 of 4)

– C2.2.1. <u>Policy</u> - Identify and assign in writing the security official for the organization who is responsible for the development and implementation of the policies and procedures required by this Regulation. While more than one individual may be given security responsibilities, a single individual must be designated as having the overall final responsibility.

#### – C2.2.2. Guidance

• C2.2.2.1. <u>Step 1: Security Official</u> - Select a security official. The ideal candidate should demonstrate competency in the following areas:

### Organization of Standards (3 of 4)

- C2.2.2.1.1. Ability to communicate effectively with and coordinate the efforts of technology and nontechnology personnel
- C2.2.2.1.2. General understanding of hardware and software security, as well as physical security.
- C2.2.2.1.3. Familiarity with the legal requirements relating to security and health care operations
- C2.2.2.1. <u>Step 2 Roles and responsibilities</u>. Assign roles and responsibilities. <u>Table C2.T6</u>. below is a general description of Security Officer roles and responsibilities.

### Organization of Standards (4 of 4)

#### HIPAA Security Officer Roles and Responsibilities

Oversee Policy Implementation, Oversight, Reviewing and Compliance

Manage the development and implementation of security policies, standards, guidelines, and procedures to ensure ongoing maintenance of the security of health information and compliance with the HIPAA Security Rule.

Identify and review the security features of existing and new computing systems to ensure that they meet the security requirements of existing policies. Review and propose changes to existing policies and procedures that reflect the existing requirements of the systems to which they apply. Periodically reassesses status and updated security standards established by the facility

Monitor day-to-day entity operations and systems for compliance.

Report to management on the status of compliance

Periodically assess current security compliance status vs. necessary status (gap analysis).

Work with management, the medical staff, the director of health information management, the privacy officer (if appointed separately), and others to ensure protection of patient privacy and confidentiality in a manner that does not compromise the entity, its personnel, good medical practice, or proper health information management practices.

# Appendix 1 (1 of 3)

### Appendix 1: Crosswalk of HIPAA to DoD Regulations

Sta	ındard	Implementation Specifications	Regulatory Guidance				
Ref#	HIPAA Safeguards and Requirements		Related DoD/MHS Policy	Related Air Force Policy	Related Army Policy	Related Navy Policy	
	Administrative						
1	Security Management Process § 164.308(a)(1)	1.0 Security Management Process	DoD 5160.54-D DoD 5200.40-I DoD 8500.1-D DoD 8500.2-I DoD 8000.1-D MHS IA Policy/Guidance Manual	AFD 33-2 AFI 33-201 AFI 33-202 AFI 33-207 AFI 41-210	AR 25-2 AR 25-2 Best Business Practices	SECNAVINST 5239.3 OPNAVINST 5239.1B OPNAVINST 5530.14C BUMEDINST 5239.1 NAVMED P-117 Ch 16	
		1.1 Risk Analysis	DoD 5160.54-D DoD 5200.40-I DoD 8500.1-D DoD 8500.2-I DoD 8510.1-M MHS IA Policy/Guidance Manual	AFD 33-2 AFI 33-201 AFI 33-202 AFSSI 5024 v.1	AR 25-2 AR 25-2 Best Business Practices	SECNAVINST 5510.36 OPNAVINST 5239.1B OPNAVINST 5530.14C BUMEDINST 5239.1	
		1.2 Risk Management	DoD 5000.1-D DoD 5000.2-R DoD 5160.54-D DoD 5200.40-I DoD 8500.1-D DoD 8500.2-I DoD 8510.1-M MHS IA Policy/Guidance Manual	AFI 33-202 AFSSI 5024 v.1	AR 25-2 AR 25-2 Best Business Practices AR 40-66	SECNAVINST 5510.36 OPNAVINST 5239.1B OPNAVINST 5530.14C BUMEDINST 5239.1	

# Appendix 1 (2 of 3)

Standard		Implementation Specifications	Regulatory Guidance					
Ref#	HIPAA Safeguards and Requirements		Related DoD/MHS Policy	Related Air Force Policy	Related Army Policy	Related Navy Policy		
		1.3 Sanction Policy	DoD 5000.2-R DoD 8510.1-M	АFI 33-129 АFJI 31-102	AR 25-2 AR 25-2 Best Business Practices AR 40-66 AR 190-16	BUMEDINST 5239.1 NAVMED P-117 Ch 16		
		1.4 Information System Activity Review	DoD 8500.1-D DoD 8500.2-I DoD 8510.1-M MHS IA Policy/Guidance Manual	AFI 33-202 AFM 33-229 AFSSI 5027	AR 25-2 AR 25-2 Best Business Practices AR 40-66	No policy available. See related DoD policy.		
2	Assigned Security Responsibility§ 164.308(a)(2)	2.0 Assigned Security Responsibility	DoD 5200.40-IDoD 8000.1- DDoD 8500.1-DDoD 8500.2-IDoD 8510.1- MMHS IA Policy/Guidance Manual	AFD 33-2AFI 33- 119AFI 33-202AFI 41-210AFJI 31- 102AFSSI 5024 v.1AFSSI 5027AFM 33-223	AR 25-2 AR 25-2 Best Business Practices AR 190-16	SECNAVINST 5239.3SECNAVINST 5510.36OPNAVINST 5239.1BOPNAVINST 5530.14CBUMEDINST 5239.1NAVMED P-117 Ch 16		
3	Workforce Security §164.308(a)(3)	3.0 Workforce Security	DoD 5200.2-D DoD 5200.2-R DoD 8500.1-D DoD 8500.2-I DoD 8510.1-M MHS IA Policy/Guidance Manual	AFI 33-202 AFSSI 5027	AR 25-2 AR 25-2 Best Business Practices AR 40-66	SECNAVINST 5510.30 BUMEDINST 5239.1		
		3.1 Authorization and/or Supervision	DoD 8500.2-I DoD 8510.1-M	No Air Force policy available. See related DoD policy.	AR 25-2 AR 25-2 Best Business Practices	No policy available. See related DoD policy.		

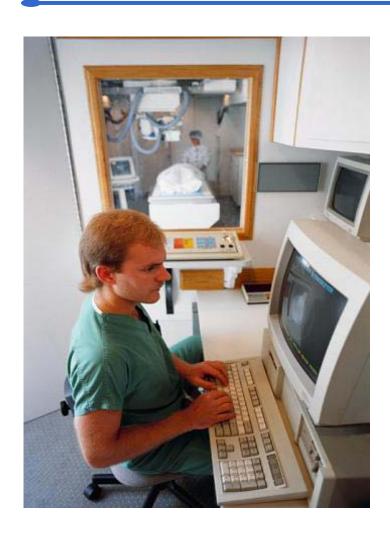
# Appendix 1 (3 of 3)

		Implementation Specifications	Regulatory Guidance				
Ref#	HIPAA Safeguards and Requirements		Related DoD/MHS Policy	Related Air Force Policy	Related Army Policy	Related Navy Policy	
		3.2 Workforce Clearance Procedure	DoD 5200.2-D DoD 5200.2-R DoD 8500.2-I DoD 8510.1-M MHS IA Policy/Guidance Manual	AFI 33-119 AFI 33-202 AFSSI 5027	AR 25-2 AR 25-2 Best Business Practices	SECNAVINST 5510.30 BUMEDINST 5239.1	
		3.3 Termination Procedures	DoD 8500.2-I DoD 8510.1-M MHS IA Policy/Guidance Manual	AFM 33-223	AR 25-2 AR 25-2 Best Business Practices	SECNAVINST 5510.30	
4	Information Access Management § 164.308(a)(4)	4.0 Information Access Management	DoD 8500.1-D DoD 8500.2-I MHS IA Policy/Guidance Manual	AFI 33-202 AFSSI 5027	AR 25-2 AR 25-2 Best Business Practices	SECNAVINST 5510.36 OPNAVINST 5239.1B NAVMED P-117 Ch 16	
		4.1 Isolating Clearinghouse Function	N/A	N/A	N/A	N/A	
		4.2 Access Authorization	DoD 8500.1-D DoD 8500.2-I DoD 8510.1-M MHS IA Policy/Guidance Manual	AFI 33-202 AFI 41-210 AFM 33-223 AFSSI 5027	AR 25-2 AR 25-2 Best Business Practices	SECNAVINST 5510.36 BUMEDINST 5239.1 NAVMED P-117 Ch 16	
		4.3 Access Establishment and Modification	DoD 8500.2-I MHS IA Policy/Guidance Manual	AFI 33-202 AFI 41-210	AR 25-2 AR 25-2 Best Business Practices	BUMEDINST 5239.1	
5	Security Awareness and Training § 164.308(a)(5)	5.0 Security Awareness and Training	DoD 8500.1-D DoD 8500.2-I DoD 8510.1-M MHS IA Policy/Guidance Manual	AFD 33-2 AFI 33-202 AFI 33-204 AFJI 31-102 AFM 33-223	AR 25-2 AR 25-2 Best Business Practices AR 190-16	SECNAVINST 5239.3 SECNAVINST 5510.30 SECNAVINST 5510.36 OPNAVINST 5239.1B OPNAVINST 5530.14C BUMEDINST 5239.1 NAVMED P-117 Ch 16	

# HIPAA Security Implementation Guide Summary

- You should now be able to:
  - Identify the purpose and organization of the Implementation Guide

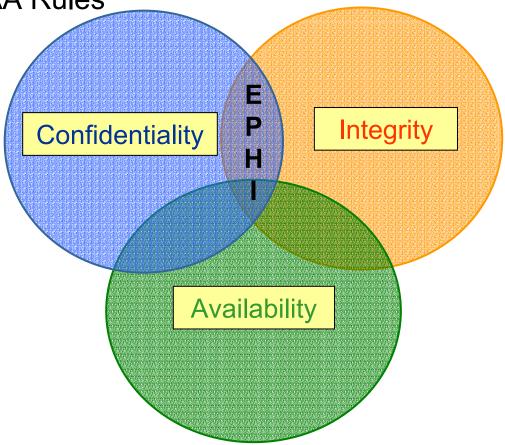
### **Objectives**



- Upon completion of this lesson, you should be able to:
  - Describe the relationship between HIPAA security and biomedical devices
  - Detail the risks of using biomedical devices
  - Identify approaches for minimizing these vulnerabilities

### **HIPAA Security Requirement**

 Must protect the confidentiality, integrity, and availability of any electronic health information that is protected under the HIPAA Rules



### Where is EPHI Found?

- Workstations
- Laptops
- Modems
- Databases
- Digitally recorded voice messages
- Computer-based facsimiles

- Servers
- Applications
- Network connections
- PDAs
- Biomedical devices
- Compact disks
- Floppy diskettes

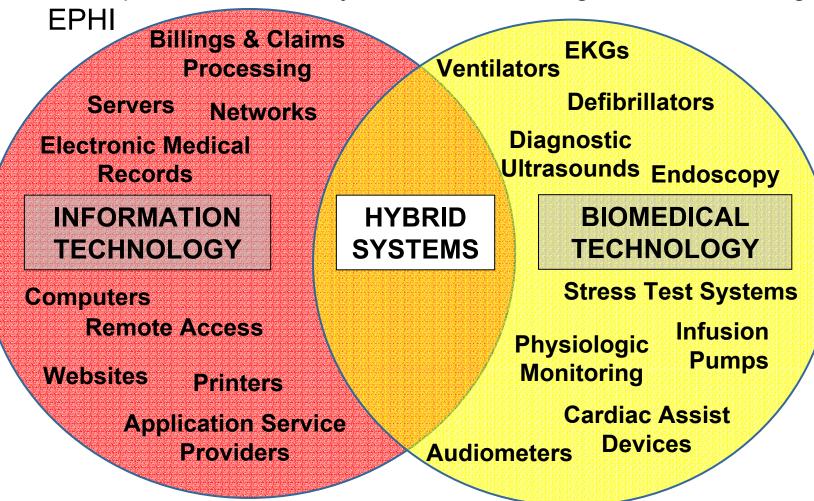
....and many more!

### **Biomedical Devices**

- A biomedical device is defined as "...an instrument which is intended for use in the diagnosis of disease, or other conditions, or in the cure, mitigation, treatment or prevention of disease..." (Food and Drug Administration, 1989)
- Majority of these instruments are highly automated and collect and store health information



Examples of devices/systems maintaining and transmitting

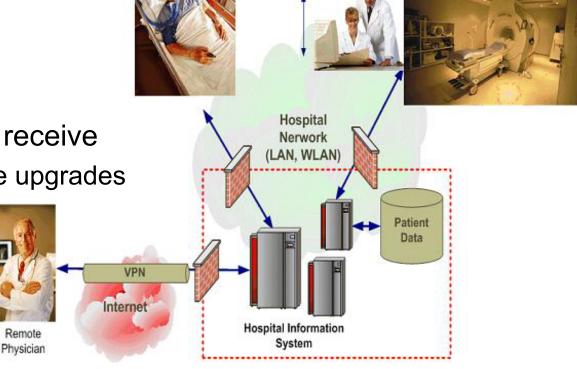


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### **Biomedical Devices and IT Systems**

Patient Monitoring

- Devices on Internet transmit
  - Location and patient info
  - Current status and setting
  - Diagnostics
  - Error codes
- Devices on Internet receive
  - Software/Firmware upgrades
  - Calibration
  - Diagnostics



Hospital Administrators

MRI

### **Historical Perspective**

- Biomedical devices utilized at MTFs operated either as stand-alone devices or as networked devices on isolated medical networks
- As such, biomedical devices with unresolved software vulnerabilities posed little or no security threat



# **Current Perspective**

- Potential threats
  - Migration of biomedical devices into interconnected networks
    - Subject to vulnerability alerts and patching requirements
  - Unresolved software vulnerabilities due to FDA regulations



# HIPAA Security and Biomedical Devices Security Risks (1 of 2)

- Biomedical devices
  - Frequently store EPHI, and therefore, must be considered when implementing a comprehensive IT security program
  - Designated and operated as special purpose computers
  - More features are being automated and increasing amounts of PHI is being collected, analyzed, and stored
  - Growing integration and interconnection of different biomedical devices and IT systems where EPHI is being exchanged

# HIPAA Security and Biomedical Devices Security Risks (2 of 2)

- "In its report covering security threats during the first quarter, McAfee's Anti-virus and Vulnerability Emergency Response Team (AVERT) said Monday that more than 1,000 new attacks aimed at software vulnerabilities emerged in the first three months of this year " (CNET)
  - Blended threats continue to constitute the most frequently reported threat
    - Combine the characteristics of viruses, worms, Trojan horses, and malicious code with server and Internet vulnerabilities to initiate, transmit, and spread an attack



- FDA requires vendors of medical devices to evaluate the impact of software changes on a medical device's safety and effectiveness before installing a security patch or upgrade
  - Vendors do not include this type of repair and testing in standard maintenance agreement
  - Evaluation entails unanticipated costs and effort
    - Most computerized medical devices are non-compliant with these FDA requirements

### **Impact: Organization**

#### Risk assessment

 MTFs must evaluate the threat to and from biomedical devices in the context of their wider approach to risk management

### Equipment lifecycle management

- Security requirements must be included in contracts or Memorandums of Understanding/Agreement
- Evaluation and remediation of vulnerabilities must be conducted before the installation of devices on the network

#### Contracts

 Must accommodate need for security upgrades to relevant equipment as appropriate and affordable

### Impact: Architecture

- Multiple, overlapping controls must be developed to support Defense-in-Depth
- Biomedical devices that acquire, distribute, display and archive medical information should be placed on their own physical or virtual segment of the network
- Precise configuration of the medical enclave depends on architectural rules of the wider network

# HIPAA Security and Biomedical Devices Recommendations (1 of 2)

- Share information on solutions amongst your peers
  - FDA Guidance related to approved vendors
  - The impact is obvious the more you share amongst your peers, the more time and resources you save
  - Information sharing should not be limited to individual Services but across the MHS



# HIPAA Security and Biomedical Devices Recommendations (2 of 2)

- Develop new requirements in vendor maintenance contracts to cover vulnerability alerts
  - Future contracts should require patches as a component of maintenance
  - Sit down with your vendor and agree on an approach to patching biomedical devices.
- NOTE: Precedence for vendors to accept this responsibility has not been established – this is especially true with legacy systems

### **Community Efforts to Address Issues**

- Healthcare Information and Management Systems Society (HIMSS)
  - Biomedical Device Security Taskforce
    - http://www.himss.org/content/files/deviceSecurity/MDSBi bliography.pdf
- National Electrical Manufactures Association (NEMA)
  - Joint Committee on Privacy and Security
    - http://www.nema.org/prod/med/security/
- NIST/WEDI/URAC
  - Biomedical Device Security Workgroup
    - http://www.urac.org/committees\_sworkgroup.asp?navid= committees&pagename=committees\_workgroups

- You should now be able to:
  - Describe the relationship between HIPAA security and biomedical devices
  - Detail the risks of using biomedical devices
  - Identify approaches for minimizing these vulnerabilities



# **Training Summary**

- You should now be able to:
  - Identify available resources to aide in Security Awareness
  - Identify available training briefings
  - Identify available resources to aide in implementation of HIPAA Security
  - Describe the relationship between HIPAA Security and biomedical devices

### Resources

- Title 45, Code of Federal Regulations, "Health Insurance Reform: Security Standards; Final Rule," Parts 160, 162 and 164, current edition
- www.tricare.osd.mil/tmaprivacy/HIPAA.cfm
- privacymail@tma.osd.mil for subject matter questions
- hipaasupport@tma.osd.mil for tool related questions
- http://www.tricare.osd.mil/tmaprivacy/Mailing-List.cfm to subscribe to the TMA Privacy Office E-News
- Service HIPAA Security Representatives

### **Additional Resources**

- RIMR
  - https://rimr.tatrc.org
- HIMSS
  - http://www.himss.org/content/files/deviceSecurity/MDSBibliograp hy.pdf
- NEMA
  - http://www.nema.org/prod/med/security
- URAC
  - http://www.urac.org/committees\_sworkgroup.asp?navid=committees&pagename=committees\_workgroups





# Please fill out your critique

Thanks!

